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TITLE

Feasibility of the Electrolarynx for Enabling Communication in the CHrOnically critically ill: The EECCHO study

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CONFLICT of INTEREST STATEMENT

The authors have no conflicts of interest to declare

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ABSTRACT

Purpose: To assess feasibility of producing intelligible and comprehensible speech with an electrolarynx; measure anxiety, communication ease, and satisfaction before/after electrolarynx training; and identify barriers/facilitators.

Methods: We included tracheostomized adults from 3 units following commands, reading English, and mouthing words. On enrolment, we measured anxiety, ease, and satisfaction with communication. We gave electrolarynx instruction for ≤5 days then 2 independent raters assessed intelligibility, sentence comprehensibility (9-point difficulty scale), and Electrolarynx Effectiveness Score (EES), and re-evaluated anxiety, communication ease, and satisfaction. Interviews explored barriers/facilitators.

Measurements and Main Results: We recruited 24 participants (Jan2015-Dec2016). Mean(SD) intelligibility was 45%(18%) words correct: 57%(21%) when facing. Mean comprehension difficulty was 6.4(2.0) overall, indicating moderate difficulty (5.5(2.5) scored visualizing). Mean EES was 2.9(1.0) (3= improved lip-reading through recognizable sounds). Anxiety decreased from median 3.8 to 2.0 (P=.007). Communication was rated easier (median 15 vs 12, P=.04) whereas satisfaction remained similar (P=.06). Facilitators included device friendliness, patient independence, and word intelligibility. Barriers were patient weakness, difficulty positioning the device, and limited sentence as opposed to word intelligibility.

Conclusion: The electrolarynx may aid intelligible speech for some tracheostomized patients if the communication partner can visualize the users face, and reduce anxiety and make patient perceived communication easier.

KEYWORDS: speech**;** communication tools; alternative augmented communication; electrolarynx; tracheostomy; intensive care

INTRODUCTION

All critically ill patients receiving mechanical ventilation experience a period of inability to speak when consciousness is regained due to the presence of an endotracheal or tracheostomy tube [1]. The inability to speak has a particularly profound impact for chronically critically ill (CCI) patients, who for the most part, are medically stable, conscious, and receiving minimal to no sedation, yet experience a protracted intensive care unit (ICU) stay [2]. Chronic critical illness is variably defined, however generally refers to patients requiring mechanical ventilation for a minimum of seven days, experiencing relative clinical stability, and who are generally tracheostomized. Inability to speak is one of the most frequent and distressing recollections of the ICU [3, 4]. Recognized consequences of speech incapacity are: significant emotional distress including anxiety, panic, anger, agitation, and loss of control; unrecognized pain; sleeplessness; and difficulty diagnosing depression and delirium [5, 6]. Anxiety associated with inability to speak can exacerbate pain [7] and may impede successful weaning from mechanical ventilation [8]. Other deleterious consequences include increased use of physical restraint, self-extubation and line removal, and injury to self and healthcare professionals due to agitation associated with inability to communicate [9]. Patient's inability to speak also creates stress and frustration for family members [10] and healthcare professionals [11, 12].

Communication impairment during hospitalization is a modifiable risk factor for adverse events and therefore has implications for care quality and patient safety [9]. Accreditation organizations have mandated demonstration of reasonable efforts to establish alternative communication strategies for patients unable to speak [13]. Progressive cuff deflation enables airflow through the vocal cords, nose and mouth with use of strategies including in-line speaking valves, digital occlusion and capping enable speech in tracheostomized patients. Despite the well-recognized deleterious consequences of speech incapacity, few studies have identified effective communication strategies that enable speech for CCI patients unable to tolerate cuff deflation due to secretion issues yet wishing to establish meaningful communication. Mouthing words, the most common approach, is often difficult to understand and subject to misinterpretation [14]. Reduced fine motor skills and impaired cognition, commonly experienced by CCI patients, impair ability to write or use communication boards or software applications. Patients may be less able to cope with these unfamiliar methods during periods of extreme physical stress and significant emotional/psychological distress such as experienced during protracted ICU admission [15]. Other communication options for promoting speech during mechanical ventilation and cuff inflation include speaking tracheostomy tubes that use either an independent gas source such as the Portex® Trach-Talk™ Blue Line® Tracheostomy Tubes (Smiths Medical, Dublin, OH) or that directs exhaled gas into the upper airway to promote airflow upwards through the larynx such as the Blom® Tracheostomy Tube (Pulmodyne, Indianapolis, IN).

The electronic artificial larynx, or electrolarynx, developed to facilitate post-laryngectomy communication in the 1940s [16], transmits electronic sound source vibrations through soft tissue, either at the neck at the level of the glottis, the cheek, or via an oral adaptor. Speech is created through movement of articulators including the lips, tongue, and jaw [17]. Following publication of two case studies that highlighted the ability of the electrolarynx for establishing speech in mechanically ventilated patients [17, 18], we sought to evaluate, using previously validated objective tools, the feasibility of the electrolarynx to produce intelligible and comprehensible speech for CCI patients with a tracheostomy and unable to tolerate cuff deflation. Secondary objectives were to measure anxiety, communication ease, and satisfaction before and after electrolarynx training as well as explore barriers and facilitators to electrolarynx use.

METHODS

Study Design, Setting, and Participants

We conducted a prospective single group feasibility study in three units: a specialized weaning centre and an ICU at a large community teaching hospital, and an ICU at a tertiary academic hospital in Toronto, Canada. Our study sample comprised patients admitted to a participating centre with a tracheostomy in situ due to prolonged mechanical ventilation and unable to tolerate cuff deflation for > one hour. Additional inclusion criteria were: (1) alert, awake, and able to follow simple commands; (2) able to read and understand English; (3) ≥ 18 years old; (4) unimpaired oral-motor capabilities and capable of mouthing words; and (5) consent to participate. Exclusion criteria were: (1) pre-existing hearing or speech impairment that seriously interfered with communication; and (2) previous diagnosis of dementia.

Study Procedures

Following informed consent, a trained research team member demonstrated electrolarynx use to participants and conducted a maximum of 5 daily training sessions of approximately 15 minutes, or until the participant was fatigued, or requested to stop. Training sessions focused on identifying the best position of the electrolarynx to facilitate speech, assisting the participant to hold and manipulate the device, over-articulation i.e., exaggerated mouth movements, and vocalizing words and short sentences. A speech language pathologist was available to assist with trouble shooting as needed. Either the Servox® Inton (Servona GmbH, Hamburg, Germany) or the Trutone™ (Griffin Laboratories, Temecula, CA) electrolarynx were used during the study.

Data Collection and Measures

To describe the study sample, we collected demographic and clinical data including age, sex, highest education level, use of hearing or visual aids, and ICU admission diagnosis, as well as clinical outcomes including decannulation success, ventilation duration, ICU length of stay and mortality. Prior to electrolarynx training, we measured anxiety, ease of communication, and satisfaction with communication. We measured anxietyusing the Faces Anxiety Scale [19], a single item scale with 5 possible responses, neutral (scored as 1) to extreme distress (scored as 5). We measured ease of communication using a six item 5-point Likert-type instrument (lower scores indicating easier communication) developed by Menzel [15] and previously used to assess communication in non-vocal ICU patients [5, 20] We measured satisfaction with communication using a 5-point Likert scale (1 very satisfied and 5 not at all satisfied).

On completion of electrolarynx training, we determined speech intelligibility and comprehensibility using one of 10 kits selected at random comprising 50 words and five sentences each comprising five words from the Assessment of Intelligibility of Dysarthric Speech (AIDS), a validated objective tool for quantifying single-word and sentence intelligibility [21]. Intelligibility is an overall measure of how speech is understood and is commonly used to document the effectiveness of an intervention to facilitate speech. Comprehensibility is defined as the listeners' perception of how difficult it is to understand an utterance [22]. As fricative consonants i.e., f, v, sh, s, z, th, h are not easily reproduced with an electrolarynx, we excluded words commencing with a fricative. We asked participants to repeat each of the 50 words printed in large font three times. One research team member showed words to the participant while simultaneously shielding from two independent raters. These two raters (one facing the participant and one facing-away to avoid visual cues from lip-reading) circled words from 12 choices in the AIDS tool. Participants then read the five word sentences, again repeating each three times. The two raters independently wrote the words heard, rated comprehensibility on a nine-point Likert scale (1 = not difficult to understand at all; 9 = very difficult to understand) [23], and scored the effectiveness of the electrolarynx for improving communication using the five point (1 = no improved intelligibility; 5= very effective, can make sentences) Electrolarynx Effectiveness Score (EES) developed by Tuinman and colleagues [24]. As we anticipated some participants might fatigue easily or have other symptoms that might interfere with testing, we then repeated the testing procedure the following day using a new set of words and sentences from the AIDS tool. Following training completion, we re-assessed anxiety, ease of, and satisfaction with, communication. Additionally, we recorded total training time, consent rates, and reasons for ineligibility.

Outcomes

Our primary outcome was feasibility of the electrolarynx for establishing successful communication defined as the ability to generate intelligible and comprehensible speech. Intelligible speech was arbitrarily defined as ≥70% of words identified correctly by raters. Ability to establish comprehensible speech was defined as a difficulty score of ≤ 5 averaged over the five sentences. Acceptability outcomes included patient perceived ease of, and satisfaction with, communication before and after electrolarynx training; and training and testing time. We considered the electrolarynx easy to use if ≥70% of participants scored ≤12 on the overall scale after training and testing. Our primary patient-reported outcome was change in anxiety before and after electrolarynx training.

Nested qualitative study

We conducted 30 to 60 minute one-on-one qualitative semi-structured interviews prior to patient discharge from the hospital to facilitate understanding of barriers and facilitators to use of the electrolarynx from the perspective of participants, family members, and clinicians involved in training and assessment. Interviews were digitally audio-recorded and transcribed verbatim. We analyzed interviews using a directed content analysis comprising predetermined barrier and facilitator categories [25]. To enhance the credibility of the analysis, two researchers independently coded the interviews and then convened to ensure agreement before aggregating coded data into barrier and facilitator classifications [26].

Ethical Considerations

The Research Ethics Boards of both participating institutions approved the study. We obtained written informed consent stressing voluntariness of participation from all participants.

Statistical Analyses

We described the study sample using descriptive statistics. For ratings of speech intelligibility and comprehensibility, we averaged scores of the two raters and report the mean (standard deviation) of the best score of the two consecutive evaluations. We compared ease of communication, satisfaction, and anxiety measured before and after training using Mann Whitney tests due to non-normal data distribution. We examined single variable correlations between patient (age, sex, ICU admission reason), training (number of sessions and total training time) and intelligibility scores using Spearman's rho, Mann Whitney, or Kruskal Wallis tests as appropriate.

RESULTS

Cohort Characteristics and Outcomes

From Jan 2015 to Dec 2016, we recruited 24 tracheostomized patients, one participant per month on average, with a consent rate of 57.5%. Most (63%) were male and admitted for medical reasons (58%); mean age was 62 years (Table 1). The cohort had a median (IQR) ventilation duration of 66 (27-66) days and an ICU length of stay of 93 (38-140) days. Of the 24 participants, 15 (62.5%) were successfully decannulated, and 3 (12.5%) died during their unit admission.

Feasibility and Patient Acceptability Outcomes

Overall mean (SD) intelligibility score was 45% (18%) words correct considering all ratings i.e. those scored facing the participant and facing-away, 25% fewer than our feasibility cut-off. Mean (SD) intelligibility score was 57% (21%) correct when assessed facing the participant (13% fewer than feasibility cut-off); 32% (19%) correct when assessed facing-away. When rated facing the participant, 68% of participants scored ≥50% correct. Overall mean (SD) comprehension difficulty was scored as 6.4 (2.0) indicating reasonable difficulty, 1.4 points higher than our feasibility cut-off of ≤ 5. Mean (SD) score was 5.5 (2.5) facing the participant, 7.3 (1.7) facing away. Mean (SD) EES was 2.9 (1.0) overall; 3.2 (1.2) facing the participant, 2.9 (0.9) facing away (3= improved lip-reading by producing recognizable sounds). Participants received an average of 3.0 (1.1) training sessions lasting 10.0 (3.9) minutes. Testing time averaged 15.7 (7.9) minutes for each testing session. We found no correlation with intelligibility score and participant age, sex, ICU admission reason, number of training sessions or total training time (all P values >0.05).

Communication was rated easier following electrolarynx training with a median (IQR) score of 12 (5-15) compared to 15 (8-18) at baseline (P=.044), although only 50% of participants scored communication ease ≤12. Overall satisfaction remained similar with a median (IQR) score of 2 (1-4) measured before training and 2 (1-2) measured after (P=.059.

Anxiety

Median (IQR) anxiety scores decreased from 3.8 (2.8-5.0) before electrolarynx training to 2.0 (1.0-2.0) on completion of intelligibility and comprehensibility testing (P=.007).

Barriers and Facilitators

We interviewed 23 patients, 7 family members and 9 clinicians. Most participants perceived the electrolaryx beneficial as it decreased anxiety and frustration during communication encounters. Facilitators to using the electrolarynx were: user friendliness, ability for independent use by the patient, and a perception of improved intelligibility of single words. Barriers to electrolarynx use included patient weakness impeding independent practice, difficulty identifying the best position to facilitate speech, and poor intelligibility of full sentences (Table 2).

DISCUSSION

We conducted this feasibility study to examine the ability of the electrolarynx to enable speech for tracheostomized patients unable to tolerate cuff deflation using rigorous methods and validated objective tools. We demonstrated the electrolarynx did enable intelligible and comprehensible speech in some participants. However, we did not achieve our feasibility end-points with an overall intelligibility score of 45% and comprehension difficulty score of 6.4. Intelligibility and comprehensibility were better when able to visualize the participant's face and the electrolarynx improved lip-reading by producing recognizable sounds as measured by the EES. Importantly, participants rated improved ease of communication after electrolarynx training and anxiety was reduced significantly. Facilitators of electrolarynx use included device friendliness, independent use, and word intelligibility. In contrast, barriers included patient weakness limiting independent use, difficulty positioning the device, and limited sentence intelligibility.

The ability of the electrolarynx to facilitate some improvement in speech intelligibility has been demonstrated in a small number of feasibility [24, 27] and case studies [17, 18]. Tuinman and colleagues [24] assessed feasibility, defined as enhanced communication experienced by the patient, family, and ICU staff as measured by the EES in 15 patients (13 endotracheal tube; 2 tracheostomy) and found the electrolarynx was effective or very effective for 6 (40%) with enhanced lip-reading in a further 2 participants. Sato and colleagues [27] measured quality of phonation using a 5-point original voice score in 29 patients and demonstrated ability to speak words in 87% of the 15 tracheostomized patients; however only two of the remaining 14 participants ventilated via an endotracheal tube could speak words. Importantly, both previous feasibility studies designed their own somewhat subjective tools to assess intelligibility and did not use a validated objective tool. In our original study design, we had intended to recruit participants ventilated via endotracheal tube yet after preliminary clinical experience with these patients elected not to include these patients in our study due to difficulties articulating with the tube in situ as well as patient-expressed discomfort with electrolarynx vibration transmitted to the endotracheal tube.

We demonstrated a significant reduction in anxiety as well as improved ease of communication following electrolarynx training, however overall communication satisfaction remained unchanged. Anxiety is a common symptom experienced during mechanical ventilation [28] and has been recommended as one of the top five symptoms that should be evaluated daily in all ICU patients [29]. Indeed, the primary finding of a meta-synthesis of qualitative studies exploring the experience of mechanical ventilation was that being dependent on health professionals, without being able to communicate, causes anxiety, fear and loneliness [4]. Anxiety negatively influences weaning outcomes through a variety of mechanisms including activation of the autonomic nervous system [30]. Reasons as to why overall communication satisfaction remained unchanged despite improved communication ease and reduced anxiety are unclear. Hypothetically, despite these improvements, communication with the electrolarynx may still not sufficiently meet patient communication needs. As inability to communicate is one of the most distressing experiences recalled by ICU survivors, particularly those requiring prolonged mechanical ventilation and tracheostomy [3] such as our participants, there is an urgent need to generate a better understanding of which communication adjuncts are most effective for which ICU patients.

Patient weakness, difficulty identifying the best position to facilitate speech, and poor sentence intelligibility were important participant reported barriers, while user-friendliness, independent use, and a perception of improved word intelligibility were important facilitators to establishing communication with the electrolarynx. Barriers to intelligible speech with speaking tracheostomy tubes using an independent gas source include occlusion of the speech lumen with secretions requiring tracheostomy change, abdominal distension due to swallowing of air administered via the speech lumen when the mouth is closed, port connection difficulties, increased resistance imposed by the tube, and physical limitations of the patient preventing manual occlusion of the air port to enable speech [31-33]. Patients with vocal cord pathology will also have difficulty creating audible speech with any speaking tracheostomy tube designs. Other speech generating options include electronic voice output communication aids, software applications, and gaze-controlled communication systems. While these devices have all shown improvement in communication ability, albeit in mostly small case series or pilot studies with poor to moderate methodological quality, all have their own specific barriers to use as a result of physical or cognitive patient abilities or device complexities [34].,.

We learned the following lessons relating to feasibility to inform future research and adoption into clinical practice. First, although some success with the electrolarynx has been reported for intubated patients, we suggest better outcomes are likely with tracheostomy patients. Second, evaluation of intelligibility without visual cues from lip-reading, as recommended in the AIDS manual, results in poor electrolarynx intelligibility and is not pragmatic in terms of understanding speech in the critically ill. Third, our feasibility targets for intelligibility and comprehensibility were ambitious. When rated facing, 68% of participants scored ≥50% of words correct, therefore ≥50% may be a more appropriate target for future studies. However, pragmatically, any improvement in speech intelligibility may have an impact on patient psychological well-being that may have led to the reduction in anxiety demonstrated in our study.

Study strengths and limitations

Major strengths of our study were multicenter participation, prospective design, consecutive accrual of eligible patients, objective assessment of intelligibility and comprehensibility using a validated tool, and qualitative exploration of barriers and facilitators. Limitations of our study were the small sample due to the limited number of eligible participants, and lack of a control group meaning our findings relating to reduced anxiety should be interpreted with caution. Assessors likely improved their ability to understand Electrolarynx speech over time thereby enhancing comprehensibility and intelligibility ratings and therefore our findings may not be reflective of untrained clinicians.

CONCLUSION

In this feasibility study, we demonstrate that the electrolarynx may improve speech intelligibility and comprehensibility, particularly when the communication partner is able to visualize the participant's face, in some, but not all tracheostomized patients. Importantly, the electrolarynx improved perceived ease of communication and reduced anxiety from the patient perspective. Further studies are required to explore combinations of communication adjuncts that are most effective for improving patient speech capacity thereby improving symptom recognition and meaningful patient participation in their health care decision making as well as reducing the psychological effects of speech incapacity.

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